Supreme Court, U.S.
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No. 97-

IN THE
Supreme Court of the United States
OCTOBER TERM, 1997

DAXOR CORPORATION, *et al.*,
Petitioners,

v.

STATE OF NEW YORK DEPARTMENT OF HEALTH, *et al.*,
Respondents.

On Petition for a Writ of Certiorari to the Court of Appeals of New York

PETITION FOR A WRIT OF CERTIORARI

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46 pp

QUESTION PRESENTED

Whether New York City licenses and authorizations to operate a blood bank and other facilities, issued for more than 25 years pursuant to a statutory delegation of regulatory authority to New York City, are a constitutionally protected "property interest" that may not be withdrawn without any hearing by State officials who have replaced the City as the licensing authority.

LIST OF PARTIES

The petitioners are Daxor Corporation; Idant Laboratories, a division of Daxor Corporation; Scientific Medical Systems/Parkmed, a division of Daxor Corporation; and Joseph Feldschuh, M.D., president and CEO of Daxor Corporation.

The respondents are the State of New York Department of Public Health; Barbara A. Debuono, M.D., Commissioner of Health of the State of New York; Lawrence S. Sturman, M.D. Ph.D., Director of the Wadsworth Center for Laboratories and Research of the State of New York Department of Health; and Jeanne V. Linden, M.D., M.Ph., Director of Blood and Tissue Resources of the State of New York Department of Health.

The parties to this proceeding are identical to those to the proceeding below.

RULE 29.6 LISTING

The petitioner Daxor Corporation is a publicly traded company listed on the American Stock Exchange with approximately 2,500 shareholders. Daxor Corporation has no parent corporation and no non-wholly owned subsidiaries.

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Respondent.

On Petition for a Writ of Certiorari
to the Court of Appeals of New York

PETITION FOR A WRIT OF CERTIORARI

The petitioners, Daxor Corporation, Idant Laboratories, Scientific Medical Systems/Parkmed, and Dr. Joseph Feldschuh, respectfully request that this Court issue a writ of certiorari to review the judgment of Court of Appeals of New York.

OPINIONS BELOW

The opinion of the Court of Appeals of New York is reported at 90 N.Y. 2d 89, 681 N.E. 2d 356 (1997), and is reproduced at Pet. App. A, pp. 1a–13a, *infra*. The opinion of the Supreme Court, Appellate Division is reported at 643 N.Y.S. 2d 57, 227 A.D. 2d 337 (N.Y. App. Div. 1996) and is reproduced at Pet. App. B, pp. 14a-17a, *infra*. The opinion of the New York Supreme Court, New York County, is unreported and is reproduced at Pet. App. C, pp. 18a-21a, *infra*.

JURISDICTION

The decision of the New York State Court of Appeals was issued on June 5, 1997. Petitioners' timely motion for reargument was denied on September 18, 1997. On November 17, 1997, Justice Ginsburg granted the petitioners' application for an extension of time within which to file a petition for writ of certiorari, to and including February 17, 1998. This Court has jurisdiction under 28 U.S.C. § 1257(a).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The constitutional and statutory provisions involved in this case are the Due Process Clause of the Fourteenth Amendment and New York Public Health Law § 574. The relevant portions of these provisions, as they appeared in 1964 and in their present form, are reproduced at Pet. App. E, pp. 23a-24a, *infra*.

STATEMENT

Introduction

Between 1964 and 1994, regulatory authority over blood banks in New York City was delegated by New York Public Health Law § 574 to the "department of health of such city pursuant to the New York city health code." Petitioners operated a licensed blood bank and clinical laboratory facilities in New York City continuously from 1971 to 1994 and were, during these 23 years, subjected by the New York City authorities to frequent and regular inspections.

Effective July 1, 1994, the City's regulatory authority was withdrawn by a statutory amendment to Section 574. The statute currently prescribes that no blood bank may be operated anywhere within New York State "unless a valid laboratory permit therefor has been issued" by the State's Department of Health. Before 1994, the State's regulatory authority over blood banks and clinical laboratories was explicitly applicable only "outside of the city of New York."

The New York State authorities have treated this amendment as totally vitiating the licenses that petitioner received from New York City. In order to continue to provide the same blood-banking services and clinical laboratory facilities that they have provided in New York City since 1971, petitioners are now required to meet the procedural standards prescribed for initial license applications, as if the petitioners were a wholly new licensee.

When petitioners applied for state licensure, the New York State Department of Health summarily denied permission to petitioners to operate the same business they had been conducting since 1971 and asserted in court that petitioner's license had not been "revoked." The State regulators insisted that petitioners had simply been denied a license under the new statutory discretionary authority conferred on the State by the recent amendment to Section 574.

A unanimous panel of the Appellate Division held that this argument "elevates form over substance" and ignores "the material property interest that petitioners derived from a continuous operating license in effect for a considerable period of time." Pet. App. B, p. 16a, *infra*; 643 N.Y.S. 2d at 59.

The New York Court of Appeals, however, reversed this decision. It held that the transfer of licensing authority from the City to the State did not affect any "property interest" of the petitioners. The Court of Appeals ruled that the licensing power conferred by New York's law "vests . . . considerable discretion in licensing medical sites" in the State regulators. Pet. App. A, p. 9a, *infra*. It therefore permitted the regulators to ignore completely the business expectancy of the petitioners based on nearly three decades of licensing by New York City authorities. That decision conflicts with cases in which this Court has recognized that an existing governmental business license is a "property interest" that may not be taken away without due process of law.

The Facts

(1) History of the blood bank. — Daxor Corporation is a publicly owned New York corporation which owns and operates a blood bank, semen bank and clinical laboratories in New York City through its divisions, Idant Laboratories and Scientific Medical Systems, ParkMed (collectively referenced herein as "Daxor"). Dr. Joseph Feldschuh is Daxor's president, chief executive officer and the medical director of its two divisions.

Daxor has operated clinical facilities and engaged in the business of tissue banking in New York City since 1971, when its facilities received licenses from the City of New York,[1] pursuant to the provisions of New York Public Health Law § 574(2), which then required any blood-bank "within the city of New York" to obtain a "laboratory permit . . . issued by the department of health of such city pursuant to the New York city health code." (The full text of § 574, as it read between 1964 and 1994, appears at Pet. App. E, pp. 23a-24a, *infra*). In 1985, Daxor opened the world's first autologous frozen (self-storage) blood bank, which enables individuals to store their own blood in advance of anticipated surgery or in the event of accident or illness which might require transfusion. Self-storage not only offers the individual the benefit of a safe supply of blood, but also enables the individual to store and use

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[1] Idant's clinical laboratories were licensed by the City in 1991. Its semen bank also began operation that year, as the nation's first public human sperm bank. The semen bank was licensed by the State Department of Health in November 1991, in accordance with regulations promulgated in 1989 which, for the first time, required the licensing of insemination facilities and semen banks. Scientific Medical Systems' laboratory, which provides laboratory tests to an ambulatory surgical center, has been licensed by the City of New York since 1972 pursuant to New York Public Health Law § 574.

"whole" blood, which includes clotting agents in plasma not present in the "red blood cell" transfusions ordinarily received in hospitals. Daxor – which provides the self-storage program to the public below cost – is the only facility in the Northeast to offer a long-term (10-year) frozen storage service.

Daxor's self-storage program was controversial with major blood-donor collection agencies, which stand to lose significant revenues from blood donations as the result of the self-storage program. This controversy resulted, among other things, in new regulations issued by the New York Department of Health to limit an individual's ability to store his or her own blood for future use.[2] *See* 10 NYCRR 58-2.6(h) (restricting use of frozen blood after one year despite FDA approval for longer use).

From its opening in 1971 through mid-1994, Daxor's facilities were inspected and approved for continued operation pursuant to their New York City licenses. Daxor's blood-banking facilities have also been annually inspected and approved by the Federal Food and Drug Administration. In connection with separate litigation, a court-appointed expert inspected petitioners' facilities and determined them to be not only safe, but superior to other facilities. Pet. App. A, p.12a, *infra*. The semen bank operated by petitioners is the only such facility

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[2] Also controversial is Daxor's proposal to require the quarantine and double testing of blood prior to transfusions. In 1985, Daxor instituted HIV testing and became the first semen bank to quarantine semen for six months in order to re-test the donor. A similar system has been instituted by Daxor for the quarantine and testing of blood donors for hepatitis and HIV – which can remain undetected in a person for up to six months. The major blood-donor collection agencies, faced with the difficulty and expense of implementing such a system, have opposed Daxor's suggestion that these procedures are necessary to ensure a safe blood supply.

in New York to be accredited by the American Association of Tissue Banks - which sets the standards of practice for the industry.[3]

(2) The new law . — Effective July 1, 1994, an amendment to New York's Public Health Law gave the New York State Department of Health exclusive jurisdiction over the licensing of petitioners' facilities. Upon receiving notice that their blood bank and clinical laboratories would no longer be permitted to operate pursuant to the licenses issued by New York City, petitioners applied to the State Department of Health for licensure of their blood bank and laboratory facilities.

(3) Notification of termination. — By letter dated September 30, 1994, the State Health Department declared its intention to deny all of petitioners' applications and terminate their existing licenses. The stated basis for this decision was the conclusion that Daxor and Dr. Feldschuh "do not have the character and competence to ensure that the [medical sites] are operated in accordance with the law, and will be so operated." This conclusion was allegedly supported by three deficiencies alleged to

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[3] Daxor's blood banks, semen bank, and clinical laboratories have not only maintained a consistent record of conformance to the industry's standards, but have also been pioneers in the industry. Idant's semen bank has provided cancer patients and others an opportunity to donate semen prior to undergoing chemotherapy or radiation therapy which renders them sterile. Since 1971, Daxor has been responsible for over 19,000 births. In 1979, the semen bank became the first to offer routine extensive testing for transmittable diseases to all depositors of semen. Many of the procedures for the preservation of human semen now used world-wide were first developed at Daxor. Daxor also developed a state-of-the-art canister carousel system for storing semen which significantly reduces the potential for semen damage that may result from use of the more traditional "cane and rack" system. Further, Daxor has recently received FDA approval to market a blood volume analyzer - the first such device to receive a U.S. patent.

have occurred at clinical laboratories operated by Idant and Scientific Medical Systems between 1986 and 1994. None of the allegations involved the blood bank, semen bank or the medical office insemination site, all of which the Department proposed to shut down.

(4) **Petitioners' response**. — By letter dated November 14, 1994, petitioners sought reconsideration of the decision to close down their facilities. They explained that the alleged deficiencies were, in large part, inaccurate and that, to the extent technical violations had occurred, appropriate steps had been taken to address them. After noting that the alleged deficiencies did not pertain to several of the facilities that the Department intended to shut down, the petitioners requested a hearing at which they would have an opportunity to substantiate their qualifications to continue to operate in New York. On March 16, 1995, the Department of Health rejected petitioners' requests. Petitioners' existing licenses were terminated and applications for new licenses were denied.

(5) **Trial proceedings**. — On March 27, 1995, petitioners commenced a state-court proceeding challenging the closure. The trial judge dismissed the petition on the ground that petitioners had received all the process they were due. Pet. App. C, pp. 18a-21a, *infra*.

(6) **The Appellate Division reverses.** — The Department of Health acknowledged in the Appellate Division that the "revocation" of an existing license would require a hearing under New York law, but it argued that this case involved only the denial of an application for a new license, which could be denied without affording notice and an opportunity to be heard. The Appellate Division unanimously reversed the trial court, holding that the petitioners had a "material property interest that petitioners derived from a continuous operating license in effect for a considerable period of time." Pet. App. B, p. 16a, *infra*. The Appellate Division observed that "[i]t is uncontested that some of petitioners' facilities have been in operation for a quarter of a century, during which time they were licensed by the New York City Department of Health," and it concluded that the State's argument "elevates form over substance." *Id.*

(7) **The Court of Appeals disagrees.** — The New York Court of Appeals held that New York state law did not "grandfather" existing city licensees and that it did not provide a hearing for "initial applications or renewals of licenses." Pet. App. A, p. 7a, *infra*. The court then said that petitioners had no "right to a hearing based on a property interest derived from years of continuous operation under the City's licensing scheme and provisional state licenses." Pet. App. A, 8a, *infra*. The court held that the "considerable discretion" vested in the Board of Health "in licensing medical sites like respondents" overrode any "legitimate claim of entitlement" by the petitioners to continue operations. Pet. App. A, pp. 8a-9a, *infra*.

REASONS FOR GRANTING THE WRIT

I

THE COURT OF APPEALS' DECISION THAT PETITIONERS HAD NO "PROPERTY INTEREST" CONFLICTS WITH RULINGS OF THIS COURT PROTECTING BUSINESSES THAT HOLD LONG-TERM LICENSES AGAINST TERMINATION OF SUCH LICENSES WITHOUT A HEARING

This Court's decisions have established that the operator of a business under a renewable license has a "property interest" in the continued maintenance of his business, and that this "property interest" may not be extinguished without minimal procedural safeguards such as either a pre-deprivation or post-deprivation hearing and an opportunity to present evidence. *See Barry v. Barchi*, 443 U.S. 55, 64 (1979); *Goldsmith v. United States Bd. of Tax Appeals*, 270 U.S. 117, 217-18 (1926); *see also Schware v. Board of Bar Examiners*, 353 U.S. 232, 238-39 (1957); *Meyer v. Nebraska*, 262 U.S. 390, 399 (1923); *Dent v. West Virginia*, 129 U.S. 114 (1889); *cf. Bell v. Burson*, 402 U.S. 535 (1971) (holding that a driver's license is property because it may be essential to the pursuit of one's livelihood). If New York State had itself granted licenses to the petitioners for the past 27 years, there would be no doubt that it could not treat the petitioners in 1994 as if they were new applicants and subject them to the unbridled discretion claimed to be applicable on the conferral of new licenses.

The Court of Appeals sought to distinguish this line of established precedent on the ground that the State had recently assumed licensing authority over blood banks in New York City and that the State Department of Health is accorded "considerable discretion" in licensing medical

sites. See Pet. App. A, p. 9a, *infra*. But this ignores the fact that petitioners had been granted continuous licensing approval from the agency to which the State had delegated its authority for the previous 27 years — the New York City Department of Health. Having deliberately chosen for many years to assign supervisory power to the City, the State may not ignore the consistent conclusions of its own designated regulator that petitioners are qualified to operate a blood bank — particularly not when the licensing of petitioners' facilities created a reasonable expectancy that the petitioners could continue their operations under State law. *See Trenton v. New Jersey*, 262 U.S. 182, 185-86 (1923) ("The city is a political subdivision of the state, created as a convenient agency for the exercise of such governmental powers of the state as may be entrusted to it."). If, in light of this history, the State Department of Health wishes to close petitioners' businesses, it must, at least, afford petitioners a hearing at which adverse factual assertions may be contested.

II

THE DECISION OF THE COURT OF APPEALS CONFLICTS WITH DECISIONS OF FEDERAL COURTS OF APPEALS THAT HAVE VIEWED THE CONTINUATION OF AN EXISTING LICENSED BUSINESS AS A "PROPERTY INTEREST" THAT CANNOT BE TERMINATED WITHOUT A DUE PROCESS HEARING

The petitioners claimed that the continued operation of the blood-bank (and other facilities) licensed for three decades by New York City is a constitutionally protected "property interest." The rejection of that claim by the New York Court of Appeals conflicts with decisions of federal courts of appeals that have recognized similar claims to continue to pursue one's livelihood or to continue to

conduct one's business as a "property interest" secured by the Fourteenth Amendment. *E.g., Herz v. Degnan*, 648 F.2d 201, 208-209 (3d Cir. 1981); *Scott v. Greenville County*, 716 F.2d 1409, 1418-1419 (4th Cir. 1983); *Phillips v. Vandygriff*, 711 F.2d 1217, 1222-23 (5th Cir. 1983), *cert. denied*, 469 U.S. 821 (1984); *Wilkerson v. Johnson*, 699 F.2d 325, 328-29 (6th Cir. 1983); *Benigni v. City of Hemet*, 879 F.2d 473, 478-79 (9th Cir. 1988).

Here again, the New York Court of Appeals took shelter in the recent statutory amendment that transferred regulatory and licensing authority from the New York City Department of Public Health to the New York State Department of Health. Although the petitioners' licenses were, in this respect, new licenses to the State regulators, they were not "new" applications from the perspective of the applicants. They had invested almost thirty years and large amounts of money in building up a well-known service in the City of New York.[4] The continuation of that service was surely a "property interest" entitled to constitutional protection.

Moreover, the New York Court of Appeals held that the Department of Health's broad "discretion" under the amended statute to consider an applicant's "competence" or "character" weighed against any property right. Federal courts of appeals have construed similar statutory provisions as limitations on agency discretion which give rise to a reasonable expectation of entitlement to a license. *See Richardson v. Town of Eastover*, 922 F.2d 1152, 1157-58 (4th Cir. 1991); *Charry v. Hall*, 709 F.2d 139,

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[4] Petitioners' semen bank and insemination facilities operated pursuant to state law, which did not require a license, for 20 years. The state licenses they received in 1991 – which respondents term "provisional" licenses – were terminated as a result of respondents' summary decision to close all of petitioners' facilities.

144 (2d Cir. 1983); *see also Memphis Light, Gas & Water Div. v. Craft*, 436 U.S. 1, 11-12 (1978) (holding that state benefits that can only be withheld "for cause" constitute property under the Fourteenth Amendment). Hence, even if petitioners were equivalent to first-time applicants, they would be entitled to minimal constitutional procedures.

III

THE ISSUE IS LIKELY TO RECUR AND REQUIRES AUTHORITATIVE RESOLUTION

Regulation and licensing are functions that States frequently delegate to municipalities. In large metropolitan centers like New York City the quality of oversight that can be provided by a municipal agency is often as good, if not better, than the supervision that may be provided by State regulators. But State legislatures frequently determine, for political or other reasons, to transfer regulatory authority from an existing municipal agency to a State agency, or even to some other local municipal or county office. This case presents the question whether such a statutory transfer can effectively eradicate all pre-existing licensing rights and privileges that businesses have come to rely upon, and subject the licensees to the boundless "discretion" of the new regulators.

This is an important issue that is likely to recur. The decision of the court below presages great confusion and will doubtless result in the summary denial of rights to future aggrieved parties. This Court should review the issue and reverse the judgment of the Court of Appeals so that the petitioners – who have introduced major advances in the fields of blood banking and semen banking – will be accorded a hearing and an opportunity to present evidence supporting their continued licensure.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX

APPENDIX A
90 N.Y.2d 89, 681 N.E.2d 356 (1997)

In the Matter of DAXOR
CORPORATION et al.,
Respondents,

v.

STATE of New York DEPARTMENT
OF HEALTH et al., Appellants.

Court of Appeals of New York.

June 5, 1997

OPINION OF THE COURT

KAYE, Chief Judge.

Appellant New York State Department of Health denied licenses to respondents to operate certain medical facilities. At issue is whether, by not first granting respondents a hearing, appellant violated their due process rights in a protected property interest and, if not, whether the denial was arbitrary, capricious or tainted by bias.

Because respondents had nothing more than unilateral expectations of renewals and favorable dispositions of their applications, we reverse the Appellate Division and hold that respondents had no property interest requiring a hearing. Further, because appellant's determination was not shown to be arbitrary, capricious or tainted by bias, we dismiss the petition.

I.

Respondent Daxor Corporation owns and operates a blood bank, semen bank and clinical laboratories in New York City through its divisions, respondents Idant and Scientific medical Systems/ParkMed (SMS). Respondent Dr. Joseph Feldschuh, Daxor's president as well as medical director of Idant and SMS, operates an artificial insemination facility on Idant's premises.

Appellant first required licensing of insemination facilities and semen banks in 1991 (*see,* Public Health Law § 4364). Idant's semen bank, in existence since 1971, has operated under a provisional license granted by appellant in November 1991 (*see,* 10 NYCRR 52-2.2). Dr. Feldschuh's insemination facility was authorized by provisional license issued in March 1993 (*id.*). Provisional licenses, which are temporary, are issued when a party applies for a permanent license, and they expire when that application is determined (10 NYCRR 52-2.2[a]).

The blood bank and clinical laboratory facilities operated by Idant and SMS were licensed by the New York City Department of Health, which from 1964 to June 30, 1994 regulated such facilities operating exclusively within its borders (*see*, Public Health Law § 574 [former (2)] [omitted pursuant to L. 1993, ch. 436]). Respondents' most recent City licenses expired, according to their own terms, on June 30, 1994.

Effective July 1, 1994, an amendment to Public Health Law § 574 gave appellant exclusive regulatory authority over licensing of these facilities State-wide (*see*, L. 1993, ch. 436). Appellant notified respondents, as it did all similar facilities about to come within its authority, that they would have to apply for State licenses to continue operation. However, they were permitted to do business,

to the extent permitted by their City licenses, until resolution of their State license applications. During the spring of 1994, respondents sought State licenses under the new regulatory scheme for all of their blood bank and clinical laboratory facilities. At that time, their applications for semen bank and insemination facility licenses were still pending, and they were operating under provisional licenses.

By letter dated September 30, 1994, appellant proposed both to deny all of respondents' applications and to terminate their provisional licenses, concluding that they "do not have the character and competence to ensure that the [medical sites] are operated in accordance with the law, and will be so operated." Appellant explained:

> "Despite numerous letters advising of specific violations, deficiency statements describing numerous substantiated violations of statutes and regulations, administrative hearings, New York City Department of Health tribunal actions, proposed and final denials of clinical laboratory and blood bank permit applications, and serious administrative charges against the semen bank [respondents] continue to operate in a manner which is in violation of existing statutes, regulations, and standards."

Supporting its determination appellant cited respondents' previous violations. These included admissions of Dr. Feldschuh and SMS that tests were performed at another medical facility without a clinical laboratory permit, together with alteration of paperwork making it appear otherwise and then, as revealed by an investigation, continuing to do so after stipulating to discontinue such testing; operating an unlicensed laboratory in Buffalo; allowing an Idant employee to operate a clinical laboratory at his New Jersey home without a permit and

altering paperwork to make it appear the testing was performed at Idant; and Idant's performance of urine pregnancy testing after authorization to do so was removed from its license.

This was not the first time respondents were denied State licensing. In mid-1990, respondents applied for a permit to run a blood bank and clinical laboratory for the 1990-1991 and 1991-1992 regulatory years. Those applications were denied on the ground that respondents had violated various State regulations. A later application for a permit for 1992-1993 was also denied after appellant's inspections revealed that the prior violations had not been corrected. Respondents' CPLR article 78 proceeding challenging the denial of those licenses was dismissed by Supreme Court and is presently before the Appellate Division.

Respondents sought reconsideration of the proposed denial urging that many of the violations complained of no longer existed or were minimal and technical in nature. After reviewing respondents' extensive additional submission, appellant denied the applications and terminated the provisional licenses.

Respondents commenced the instant article 78 proceeding alleging that the determination was biased, arbitrary and capricious, and that by failing to provide a hearing appellant had deprived them of due process. Supreme Court denied respondents' petition but the Appellate Division reversed, concluding that the licenses respondents had previously received from the City constituted a protected property interest which could not be taken away without a hearing. Characterizing appellant's actions as a revocation, the court examined the legislative history of the amendment to the Public Health Law, and found no intent to eliminate existing licenses without a

hearing. Because respondents had not been afforded a hearing, the court annulled appellant's determinations – including those regarding the semen bank and insemination facility licenses, which the Appellate Division did not otherwise address. We granted leave to appeal, and now reverse.

II.

Although amended Public Health Law § 574 did not explicitly confer State licenses on existing City licensees, respondents urge that when the State stepped into the City's role they were, in effect, "grandfathered" into State licenses.[1] Thus, in their view, appellant's denial of licenses was tantamount to revocation, which as a matter of law requires a hearing (*see*, Public Health Law § 577[3]). The notion that appellant's action constituted a revocation was central to the Appellate Division decision, as it is to respondents' argument before us.

The July 1, 1994 amendment of Public Health Law § 574, removing clinical laboratories and blood banks from City regulation and placing them exclusively within appellant's authority, had several purposes. To be sure, one purpose was – as respondents emphasize – to ease the regulatory burden on license applicants and avoid duplicative and inconsistent regulations (Mem of Legislative Representative of City of New York, Bill Jacket, L. 1993, ch. 436, at 27-28 [reprinted in 1993 McKinney's Session Laws of N.Y., at 2619-2620]). But the amendment served other important purposes as well,

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[1] This argument applies only to the blood bank and clinical laboratories. Respondents' insemination facility and semen bank were at all relevant times regulated by appellant, not by the City Department of Health.

among them more closely monitoring the qualifications of such facilities and making the requirements for certification more stringent, to comply with Federal law (*id.* ["enforcement of applicable laws and regulations against non-compliant laboratories and blood banks will be enhanced when, as envisioned by this legislation, (the) State, with its larger and more extensive investigative and legal resources, takes over the City's program"]; Letter of Senator Michael J. Tully, Jr., in support, Bill Jacket, L. 1993, ch. 436; Mem of Senator Michael J. Tully, Jr., in support of L. 1993, ch. 436, 1993 N.Y. Legis. Ann., at 315-316).

As made clear in Public Health Law § 570:

> "[i]t is the purpose of this title to promote the public health, safety and welfare by requiring the licensure of clinical laboratories and blood banks, by establishing minimum qualifications for directors, and by requiring that the performance of all procedures employed by clinical laboratories and blood banks meet minimum standards accepted and approved by the department."

Thus, neither the explicit language of the amendment nor the legislative intent to closely monitor these medical facilities supports respondents' contention that City licensees automatically gained State licenses.

Indeed, reading Public Health Law § 574 together with the other sections of the Public Health Law governing State licensing confirms the opposite conclusion. Public Health Law § 575(2) states that appellant shall not issue a permit for a blood bank or clinical laboratory

> "unless a valid certificate of qualification in the category of procedures for which the permit is sought has been issued to the director pursuant

> to the provisions of section five hundred seventy-three of this title, and unless the department finds that the clinical laboratory or blood bank is competently staffed and properly equipped, and will be operated in the manner required by this title" (*id.*).

Were respondents' view followed, those requirements would have to be ignored, as would the requirements of annual renewal (Public Health Law § 575[4]) and the automatic voiding of a license should there be a change in director, location or ownership of the laboratory (Public Health Law § 575[6]).

Reading the amendment as respondents urge would lead to another result the Legislature could not have intended: entities previously licensed by the City would be licensed State-wide with no review by appellant. Especially considering respondents' prior unsuccessful attempts to obtain State licensing, "grandfathering" them would provide an unwarranted windfall.

We therefore conclude that respondents were not automatically licensed by the State. They were at best seeking renewals of their licenses to operate their clinical laboratories and blood bank,[2] and were initial applicants for insemination facility and semen bank licenses. While existing licenses cannot be revoked without a hearing, there is no similar right for initial applications or renewals of licenses (*see*, Public Health Law § 577[3]; *Matter of Richard I, Inc. v. Ambach*, 90 A.D.2d 127, 457 N.Y.S.2d 583, *affd for reasons stated below*, 61 N.Y.2d 784, 473 N.Y.S.2d 165, 461 N.E.2d 302, *cert denied* 469 US 822,

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[2] Indeed, even if the Public Health Law had not been amended, respondents would have had to seek renewal of their City licenses, which expired June 30, 1994.

105 S. Ct. 97, 83 L.Ed.2d 43; *Matter of 125 Bar Corp. v. State Liq. Auth.*, 24 N.Y.2d 174, 178-180, 299 N.Y.S.2d 194, 247 N.E.2d 157; *Matter of Fink v Cole*, 1 N.Y.2d 48, 51-52, 150 N.Y.S.2d 175, 133 N.E.2d 691).

III.

Respondents alternatively claim the right to a hearing based on a property interest derived from years of continuous operation under the City's licensing scheme and provisional State licenses. Again, their contentions lack merit.

As explained in *Board of Regents v. Roth,* 408 U.S. 564, 92 S.Ct. 2701, 33 L.Ed.2d 548:

> "To have a property interest in a benefit, a person clearly must have more than an abstract need or desire for it. He must have more than a unilateral expectation of it. He must instead, have a legitimate claim of entitlement to it. * * * "Property interests, of course, are not created by the Constitution. Rather, they are created and their dimensions are defined by existing rules or understandings that stem from an independent source such as state law – rules or understandings that secure certain benefits and that support claims of entitlement to those benefits" (*id.*, at 577, 92 S. Ct. at 2709).

In considering whether a legitimate claim of entitlement, or right, is granted by State law, "the focus is on the relevant statute, regulation, or contract establishing eligibility for the benefit at issue" (*Matter of Medicon Diagnostic Labs. v. Perales*, 74 N.Y.2d 539, 545, 549 N.Y.S.2d 933, 549 N.E.2d 124). Thus, the focus of

respondents' claimed property interest must be on the laws from which the licenses derive.

As has been noted in other contexts, what is central to this analysis is whether the law accords discretion to the authority: property interests do not arise in benefits that are wholly discretionary (*see*, *e.g.*, *Matter of Doe v. Coughlin*, 71 N.Y.2d 48, 55, 523 N.Y.S.2d 782, 518 N.E.2d 536 [prisoners had no liberty interest in conjugal visit program where 15 discretionary factors were consulted before allowing a visit]; *Yale Auto Parts, Inc. v. Johnson*, 758 F.2d 54, 59 [2d Cir.] [no entitlement to location approval certificate for junkyard where Department of Motor Vehicles retained discretion to deny]; *RRI Realty Corp. v. Incorporated Vil. of Southampton*, 870 F.2d 911 [2d Cir.], *cert denied* 493 US 893, 110 S. Ct. 240, 107 L.Ed.2d 191 [no entitlement to building permit because of authority's wide discretion]).

While the "theoretical possibility of discretionary action does not automatically classify an application for a license or a certificate as a mere 'unilateral hope or expectation'" (*Sullivan v. Town of Salem*, 805 F.2d 81, 85 [2d Cir.]), here we do not need to consider precisely how much discretion defeats an entitlement because it is clear that the law vests appellant with considerable discretion in licensing medical sites like respondents'.

Indeed, only those blood banks and clinical laboratories appellant determines to be "competently staffed and properly equipped," and "operated in the manner required by [the Public Health Laws]" (Public Health Law § 575[2]) may receive licenses. Moreover, Public Health Law § 575[2] also requires that appellant have awarded a valid certificate of qualification (*see*, Public Health Law § 573) to the director of the clinical laboratory or blood bank. Such certificates issue only to a person who "possesses the

character, competence, training, and ability to administer properly the technical and scientific operation of a clinical laboratory or blood bank, including supervision of procedures and reporting of findings of tests" (Public Health Law § 573[2]).

Similarly, licenses for an insemination facility and semen bank issue only when appellant finds that "the premises, equipment, personnel, rules and by-laws, and standards of service are fit and adequate and that the bank or storage facility will be operated in the manner required by this article" (Public Health Law § 4364[3]). Among the factors that appellant is to consider before approving a license is the "character and competence of the operator, its officers, directors, principal stockholders and controlling persons, including the quality of care provided through any health care entities operated or controlled by such persons" (Public Health Law § 4364[4][f]) - again plainly discretionary determinations.

Respondents' provisional licenses also did not give rise to a property right. Provisional licenses are temporary and expire a period of time after a denial of the application for a permanent license (10 NYCRR 52-2.2[a]). Further, they may be revoked at any time without a hearing if appellant finds that the facility is not operated in substantial compliance with the provisions of 10 NYCRR 52-2.5 (*see*, 10 NYCRR 52-2.2[e]).

To be contrasted against these laws are instances where the administrative body was without discretion to deny an application and thus the applicant had an entitlement to the license sought. In *Walz v. Town of Smithtown*, 46 F.3d 162, 168 [2d Cir.], *cert denied* __ U.S. __, 115 S.Ct. 2557, 132 L.Ed.2d 810, for example, the court examined the authority of the Superintendent of Highways to deny an excavation permit and noted that upon

the applicants providing certain information on the appropriate form, the permit "shall be issued in the name of the Superintendent of Highways of the Town of Smithtown." Because the Superintendent was without discretion to refuse to issue a permit, the court held that the applicants had a property right in the permit. Nor is this case like *Sullivan v. Town of Salem,* 805 F.2d 81, *supra*, where the licensing authority denied a license based on a requirement not contained within its enabling statute, rather than one as to which it had discretion. Here, appellant indisputably relied on discretionary grounds within its statutory authority.

Thus, respondents had no property interest entitling them to a due process hearing.[3]

IV.

Respondents are, of course, entitled to administrative review that is not arbitrary, capricious or tainted by bias. They have not shown they were denied that.

Although the record demonstrates that respondents have not complied with the applicable laws and regulations in the past, they urge that any violations have been rectified; that certain violations were only minimal and technical in nature; that the violations applied only to the clinical laboratories and should not affect the status of the other applications; and that based on a recent inspection conducted by an independent Judge-appointed party for a related litigation, respondents' facilities were deemed not

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[3] We note that even if a property interest were found, that would not necessarily entitle respondents to a hearing (*see, Mathews v. Eldridge*, 424 U.S. 319, 335, 96 S. Ct. 893, 903, 47 L.Ed.2d 18 [establishing four-factor balancing test to determine the amount of process due to an individual with a protected interest]).

only safe but also superior to other facilities. Thus, argue respondents, appellant's denial of the applications was arbitrary and capricious.

These arguments miss the mark. The issue here is not whether respondents corrected any earlier deficiencies, or how well their facilities function now. Appellant denied the applications because respondents "do not have the character and competence to ensure that the [medical sites] are operated in accordance with the law, and will be so operated" (*see* Public Health Law § 573[2]; § 575[2]; § 4364[4][f]; 10 NYCRR 52-2.5), a determination that is entitled to deference (*see*, *Matter of Medical Malpractice Ins. Assn. v. Superintendent of Ins.*, 72 N.Y.2d 753, 763, 537 N.Y.S.2d 1, 533 N.E.2d 1030, *cert denied* 490 U.S. 1080, 109 S. Ct. 2100, 104 L.Ed.2d 661 ["It is axiomatic that a court reviewing the determination of an agency may not substitute its judgment for that of the agency and must confine itself to resolving whether the determination was rationally based."]). Given the record with respect to the clinical laboratories, and Dr. Feldschuh's central role in all the facilities, we cannot say that appellant acted arbitrarily or capriciously in denying the licenses.

Finally, while respondents describe an elaborate regulatory conspiracy against them, they rely on allegations lacking the requisite factual support (*see*, *Matter of Warder v. Board of Regents*, 53 N.Y.2d 186, 197, 440 N.Y.S.2d 875, 423 N.E.2d 352, *cert denied* 454 U.S. 1125, 102 S. Ct. 974, 71 L.Ed.2d 112 ["(A) mere allegation of bias will not suffice. There must be a factual demonstration to support the allegation of bias."]). And in any event, as the record reveals independent reasons that fully support appellant's determination, respondents have failed to show that alleged bias was the cause of the denial (*id.*, at 197, 440 N.Y.S.2d 875, 423 N.E.2d 352 [there must be proof that the challenged regulatory "outcome flowed from

(bias)"]).

Respondents' remaining arguments are without merit.

Accordingly, the order of the Appellate Division should be reversed, with costs, and the petition dismissed.

TITONE, BELLACOSA, SMITH, LEVINE, CIPARICK and WESLEY, JJ., concur.

APPENDIX B
643 N.Y.S.2d 57, 227 A.D.2d 337 (N.Y.App. Div. 1996)

In re Application of DAXOR CORPORATION, et al., Petitioners-Appellants,

For a Judgment, etc.,

v.

The STATE of New York DEPARTMENT OF HEALTH, et al., Respondents-Respondents.

Supreme Court, Appellate Division
First Department

May 30, 1996

Before SULLIVAN, J.P., and ELLERIN, RUBIN, KUPFERMAN and WILLIAMS, J.J.

MEMORANDUM DECISION.

Order of the Supreme Court, New York County (Harold Tompkins, J.), entered July 19, 1995, which denied petitioners' applications, pursuant to CPLR article 78, to annul respondent's denial of blood bank, clinical laboratory and tissue bank permits, and dismissed the petition, unanimously reversed, on the law, without costs, the petition granted and the determination annulled.

Petitioner Idant Laboratories, a division of petitioner Daxor Corporation, operated a blood bank, a semen bank and a clinical laboratory in New York City. Petitioner Scientific Medical Systems/Parkmed (SMS), also a division

of Daxor Corporation, ran a clinical laboratory. Petitioner Joseph Feldschuh, M.D., who operated an insemination site located on Idant's premises, is Daxor's president and the medical director of both Idant and SMS. Daxor is a publicly traded company with approximately 5 million outstanding shares of common stock and about 2,500 shareholders. SMS was acquired by Daxor in 1972. Idant opened its semen bank in 1971 and its blood bank in 1985.

This controversy arises out of the transfer of regulatory authority over clinical laboratories and blood banks located in the City of New York from the New York City Department of Health to the New York State Department of Health (L1993, ch. 436 [effective July 1, 1994]). At issue is whether, as respondent New York State Department of Health maintains, petitioners were properly considered to be operating under conditional State licenses which can be terminated without a hearing or whether, as petitioners assert, they have a protected property interest in their licenses which must be accorded procedural due process (Public Health Law § 577[3]).

It is uncontested that some of petitioners' facilities have been in operation for a quarter of a century, during which time they were licensed by the New York City Department of Health. However, it is respondent's position that, following consolidation of regulatory authority in the New York State Department of Health, petitioners assumed the status of initial applicants for State operating licenses. Respondent regards their operation during this period to be authorized by temporary State permits which, it asserts, are subject to termination without a hearing. It is respondent's contention, on appeal, that the New York State Department of Health "did not, by denying the application, revoke petitioners' old New York City license. Rather, in 1993, the State Legislature abolished

the City's licensing authority and the future validity of any then existing City licenses."

Nothing in the legislation itself or in the memorandum of the Legislative Representative of the City of New York in support of the amendment (1993 McKinney's Session Laws of NY, at 2619), suggests that any such abolition of existing operating licenses was intended. The memorandum notes that the bill "would create one system for the regulation of clinical laboratories and blood banks in New York State" so that "clinical laboratories and blood banks which operate both in New York City and elsewhere in New York State will need but a single permit." (*Ibid.*) By eliminating unnecessary duplication, the legislation will eliminate "the extra cost and labor involved in maintaining two permits" and provide greater consistency in that "a single set of regulations will govern the conduct of clinical laboratories and blood banks in New York State." (*Id.*, at 2620.) The memorandum notes that the legislation amends sections 572, 573, and 574 of the Public Health Law "to phase-out [sic] references to certificates of qualification and permits issued by the New York City Department of Health" by requiring all such facilities "to obtain a permit from the New York State Department of Health". (*Id.*, at 2619.)

Respondent's argument elevates form over substance, ignoring the material property interest that petitioners derived from a continuous operating license in effect for a considerable period of time (*Board of Regents of State Colleges v. Roth*, 408 U.S. 564, 576-77, 92 S.Ct. 2701, 33 L.Ed.2d 548; *Reed v. Village of Shorewood*, 704 F.2d 943, 948). That the State Legislature *may* abolish a license without providing the licensee a hearing (e.g., *New York State Trawlers Assn. v. Jorling*, 16 F.3d 1303), as respondent asserts, is of little significance. We conclude that the Legislature has not done so in this instance, but has

merely provided that the State Department of Health assume responsibility for the regulation of existing facilities, formerly subject to regulation by the New York City Department of Health. As New York State law requires that the licensee be given a hearing before revocation of a permit or certificate, petitioners' due process rights were violated, and the determination of respondent Department of Health must therefore be annulled.

APPENDIX C
Unreported

SUPREME COURT, NEW YORK COUNTY
IAS PART 13

----------X

Application of DAXOR CORPORATION, et al.,

Petitioner

Index No. 107564/95

For a Judgment Pursuant to CPLR Article 78

Motion Submitted
June 23, 1995

-against-

THE STATE OF NEW YORK DEPARTMENT OF HEALTH, et al.,

Respondents.

----------X

HAROLD TOMPKINS, JUSTICE:

This petition seeks to set aside respondent State of New York Department of Health's March 16, 1995 denial of outstanding permit applications for petitioner Daxor, its subsidiaries and owners and the termination of its provisional permits.

Daxor and its affiliated entities operate blood banks, tissue banks, semen banks and clinical laboratory institutions. The petitioner asserts that it is entitled to a full due process hearing prior to any determination not to issue licenses, that Department of Health's failure to hold such a

hearing is arbitrary and capricious, that Daxor and its affiliated entities were operating properly and respondent Department of Health is biased against them.

Department of Health contends that it has properly evaluated Daxor and its affiliated entities and has determined, based upon a history of past violations in the operation of blood banks, failure to employ properly licensed personnel, testing specimens without a license, specimen tests outside the clinical laboratory and operating without a valid permit. The agency asserts that this activity amounts to a pattern of unwillingness or inability to obey the laws and regulations on matters of public health and it is warranted in concluding that Daxor and its affiliated entities, having failed to abide by the applicable laws and regulations in the past, will ignore their legal obligations in the future. The Department of Health states that since petitioners have not shown that they will operate the facilities as mandated by law, they have not shown a right to a license. The Department of Health further claims that no legal entitlement to a license exists and therefore there is no necessity for a hearing and that since the temporary licenses expire by lapse of time, no hearing is required as to those licenses.

The court starts by recognizing that respondent Department of Health is the agency responsible for public health, for enacting human tissue, blood and sperm bank regulations, for interpreting these regulations in its enforcement with the guiding principle of the health of the public at large, it is therefore appropriate to give its judgment due deference, see Matter of Deas v Levitt, 73 NY2d 525 (1989); Matter of Berenhaus v Ward, 70 NY2d 436 (1988).

Petitioner Daxor has not shown either bad faith or improper motives in the respondent's enforcement

activities. In reviewing petitioner's claim for licenses, it is reasonable for the agency to consider the past activity of petitioner and its affiliated entities, see Tony's Barge Service, Inc. v. Town Board of Brookhaven, 210 AD2d__ (4th Dept. 1994), 619 NYS2d 341, lv. denied 85 NY2d 807 (1995). It has chosen to view the prior violations as a pattern of activity that makes it unlikely that petitioner will observe the legal and regulatory requirements in the future. Particularly in a matter of public health, the court should rely on the specialized expertise of the regulatory authority, see Berenhaus, supra.

In reviewing the claim of a violation of due process, the court must determine what process was due, see Mathews v. Eldridge, 424 U.S. 564 (1976); Board of Regents v Roth, 408 U.S. 564 (1972). The petitioner's applications for licenses does not give rise to any property interest at least until it is granted a license and a temporary time limited license also necessarily does not create an enduring property right, see Gagliardi v Town of Pawling, 18 [F.3d] 188 (2nd Cir. 1994). Even assuming petitioner has a protectable expectancy interest, weighing the expectancy interest of petitioner against the strong public interest of laboratories serving public health regulations, the court finds that petitioner has received all the process it was due, see Tony's Barge, supra; Matter of Keith H., 188 AD2d 81 (2nd Dept. 1993). The petition is dismissed and the application to annul the Health Department's determination to revoke the temporary licenses of petitioner and to deny all its pending license applications is denied.

This decision constitutes the order of this court and the Clerk has advised counsel for both parties of this order.[1]

Dated: July 17, 1995.

/S/ Harold Tompkins
J. S. C.

FOOTNOTE

1. Pursuant to a conference call with the parties on July 12, 1995, expiration of plaintiff's licenses is extended five business days after the date of this decision.

APPENDIX D
Unreported

State of New York,
Court of Appeals

At a session of the Court, held at Court of Appeals Hall in the City of Albany on the eighteenth day of September 1997

Present, HON. JUDITH S. KAYE, *Chief Judge, presiding*

Mo. No. 1008

In the Matter of Daxor Corporation, et al.,

Respondents,

v.

The State of New York Department of Health, et al.,

Appellants.

A motion for reargument to the Court of Appeals in the above cause having been heretofore made upon the part of the respondents herein and papers having been submitted thereon, and due deliberation thereupon had, it is

ORDERED, that the said motion be and the same hereby is denied.

/S/ Stuart M. Cohen
Stuart M. Cohen
Clerk of the Court

APPENDIX E

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

1. The Due Process Clause of the Fourteenth Amendment to the United States Constitution provides:

> [N]or shall any State deprive any person of life, liberty, or property, without due process of law . . . .

2. New York Public Health Law § 574, L.1993, ch. 436 (effective July 1, 1994) provides:

> No person shall own or operate a clinical laboratory located in or accepting specimens from New York state or own or operate a blood bank which collects, processes, stores and/or distributes, human blood, blood derivatives or blood components, in New York state unless a valid permit has been issued as provided in section five hundred seventy-five of this title. A permit shall be issued authorizing the performance of one or more procedures or services within one or more categories. A separate permit shall be required for each facility at which clinical laboratory tests are to be performed or at which a blood bank is to be operated, provided, however that the department may adopt regulations not inconsistent with the federal clinical laboratory improvement act of nineteen hundred eighty-eight authorizing an owner to operate more than one facility under a single permit.

3. Prior to the 1994 amendment, New York Public Health Law § 574, L.1964, ch. 217, § 1, provided:

> 1. No person shall own or operate a clinical laboratory or blood bank, solicit or accept a specimen for laboratory examination or collect, process or store human blood or blood derivatives, outside of the city of New York, nor shall the state of New York operate a clinical laboratory or blood bank, unless a valid laboratory permit therefor has been issued as provided in section five hundred seventy-five of this title. A permit shall be issued authorizing the performance of one or more laboratory procedures or one or more categories of such procedures. A separate permit shall be required for each facility at which laboratory tests are to be performed or at which a blood bank is to be operated.
>
> 2. No person, other than the state of New York, shall own or operate a clinical laboratory or blood bank, solicit or accept a specimen for laboratory examination, or collect, process or store human blood or blood derivatives, within the city of New York, unless a valid laboratory permit therefor has been issued by the department of health of such city pursuant to the New York city health code or he has otherwise complied with the provisions of that code.
>
> (Added L.1964, c. 217 § 1; amended L.1969, c. 407, § 75; L.1978, c. 655, § 85; L.1986, c. 801, § 2.)

No. 97-1345 (2)

Supreme Court, U.S.
FILED
MAR 18 1998
CLERK

IN THE

Supreme Court of the United States

October Term, 1997

DAXOR CORPORATION, et al.,

Petitioners,

- v. -

STATE OF NEW YORK DEPARTMENT OF HEALTH, et al.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE COURT OF APPEALS OF THE STATE OF NEW YORK

BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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Dated: March 18, 1998

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Question Presented

Whether certiorari should be granted to examine petitioners' Due Process claim of entitlement to State licenses to operate various medical facilities, where (1) petitioners operated those facilities prior to 1994 pursuant to either provisional State licenses or limited licenses annually issued by the City of New York; (2) the New York State Legislature withdrew New York City's authority to issue licenses in 1994, and mandated that no such facility operate in New York State unless licensed by the New York State Department of Health (DOH); and (3) DOH regulations provided petitioners with no assurance that their license applications would be granted.

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No. 97-1345

In The

Supreme Court of the United States

October Term, 1997

DAXOR CORPORATION, et al.,

Petitioners,

v.

STATE OF NEW YORK DEPARTMENT OF HEALTH, et al.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE COURT OF APPEALS OF THE STATE OF NEW YORK

Brief in Opposition to Petition For Writ of Certiorari

Opinions Below

Respondents adopt the statement of opinions below set forth in the petition for a writ of certiorari. (Pet. 2).[1]

Jurisdiction

Respondents adopt the statement of jurisdiction set forth in the petition for a writ of certiorari. (Pet. 2).

Statement

A. New York State Regulation of Clinical Laboratories, Blood Banks and Tissue Facilities

Recognizing the substantial public interests and health concerns affected by the operation of blood banks, clinical laboratories, semen banks and insemination sites in New York State, the New York Legislature has provided for the regulation of these entities by the State Department of Health ("DOH"). *See*, New York Public Health Law ("PHL") §§ 570 *et seq.* (McKinney Supp. 1997)(regulation of blood banks and clinical laboratories); PHL §§ 4360 *et seq.* (McKinney Supp. 1997)(regulation of tissue banks, including semen banks and insemination sites). As part of the regulatory process, the Legislature has directed DOH to issue operating permits to such medical sites (PHL § 574; PHL § 4364[1]), and has prohibited issuance of permits to any facility unless DOH determines that the facility will be operated in the manner required by the State's public health laws and regulations. PHL §575(2) (clinical laboratories and blood banks); PHL § 4364(3) (tissue banks). DOH has issued regulations implementing this statutory

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[1] Numbers in parentheses preceded by "Pet." refer to pages in the petition for a writ of certiorari in No. 97-1345.

mandate. *See, e.g.*, N.Y. Comp. Codes R. & Regs. tit. 10 (hereafter "10 NYCRR") § 52-2.5 (5) (1995) (licenses to operate a tissue bank will be denied where the director of the medical site does not have the "character and competence to ensure that [the facility] is ... operated in accordance with the law.").

Under the Public Health Law, each specific site at which a laboratory tests materials or performs tissue banking must obtain a separate operating permit, which must specify the laboratory procedures or type of tissue banking authorized. PHL §§ 574; 575(1)(5)(6); 4364(2). The Legislature has limited the term of laboratory and blood banking permits to one year. PHL § 575(4).

B. The City of New York's Blood Bank and Clinical Laboratory Licensing Authority and Its Repeal

Between 1964 and 1994, blood banks and clinical laboratories operating exclusively within New York City were licensed by the City; laboratories operating outside New York City were licensed by the State. *See* PHL § 574(2) (repealed 1993). In 1993, the Legislature amended this regulatory system, abolishing the City licensing system and requiring all facilities to obtain more general State licenses or to cease operation. *See* 1993 N.Y. Laws, Chapter 436. Chapter 436 was signed into law on July 26, 1993, and became effective on July 1, 1994.

As noted by the New York State Court of Appeals in its decision below, the purpose of this statutory amendment was not merely "to ease the regulatory burden on license applicants and avoid duplicative and inconsistent regulations[.]" (Pet. App. 5a).[2] Rather, "the amendment served other purposes as

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[2] "Pet. App." denotes the appendix to the petition for a writ of certiorari in No. 97-1345.

well, among them more closely monitoring the qualifications of such facilities and making the requirements for certification more stringent, to comply with federal law[.]" (Pet. App. 5a-6a).

To aid the transition, DOH informed all blood banks and clinical laboratories operating under City licenses -- including petitioners -- that, upon their application for a State license, they could continue to operate in New York City, but not in the State at large, "until final issuance or denial of your State credentials, i.e., your certificate of qualification or your laboratory permit." (R. 585)[3] (emphasis added).

C. New York State Regulation of Semen Banks and Insemination Sites

Prior to 1989, neither New York City nor New York State regulated the operation of semen banks and artificial insemination sites. 10 NYCRR Subpart 58-7 (1989), which was succeeded by 10 NYCRR Subpart 52-2 (1991). Following the institution of a State permit requirement in 1991, operators of these facilities both within and outside New York City were eligible to apply to DOH for provisional licenses while their applications were evaluated. 10 NYCRR § 52-2.2(e). Under DOH regulations, such provisional licenses are issued on a temporary basis, expire upon determination of the underlying application, and may be revoked at any time, without a hearing, if DOH "finds that the [site] is not operated in substantial compliance with the applicable [DOH regulations]." *Id.*.

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[3] "R" denotes the record on review in the New York State Court of Appeals.

D. Petitioners' Licensing History

Petitioner Daxor Corporation owns and operates a blood bank, semen bank and clinical laboratories in New York City through its divisions, petitioners Scientific Medical Systems/Parkmed ("SMS") and Idant Laboratories. Prior to July 1, 1994, petitioners operated their blood bank and clinical laboratories pursuant to City of New York permits. The last of those permits were issued on January 26, 1994 and expired, by their express terms, on June 30, 1994, the date that the City licensing system ceased to exist. Petitioners at no time held a City permit of a term exceeding one year, and all permits were subject to annual reapplication.

During the time petitioners were licensed to operate by the City, they periodically applied to DOH for State operating licenses. However, those applications were consistently denied by DOH on the same grounds which led DOH to deny the applications in the instant matter, i.e., a determination that petitioners lacked the character and competence to ensure that their facilities would be operated in conformance with the law. (R. 715-19). At least two of those determinations were also challenged in the New York State Courts. (R. 715-19).

Between 1991 and 1995, petitioners operated their semen bank and insemination site pursuant to provisional licenses issued by DOH under 10 NYCRR § 52-2.2.

E. DOH's Denial of Petitioners' License Applications and the Administrative Proceedings Below

Petitioners submitted a series of permit applications to DOH for the operation of their semen bank, insemination site, blood bank, and clinical laboratories between 1991 and mid-1994. DOH denied all four of petitioners' applications for State operating licenses. As set forth in a letter sent to petitioners on

September 30, 1994 (the "Denial Letter"), DOH based its denial upon the determination that petitioners "do not have the character and competence to ensure that the [medical sites] are operated in accordance with the law, and will be so operated." (R. 111, Denial Letter at p. 2). In making this determination, DOH reviewed its extensive prior experience with Daxor Corporation and its operator, Dr. Feldschuh, and noted that:

> Despite numerous letters advising of specific violations, deficiency statements describing numerous substantiated violations of statutes and regulations, administrative hearings, New York City Department of Health tribunal actions, proposed and final denials of clinical laboratory and blood bank permit applications, and serious administrative charges against the semen bank, [petitioners] continue to operate in a manner which is in violation of existing statutes, regulations and standards.

(*Id.*). Violations cited by DOH in its letter included:

(i) On July 28, 1986 Dr. Feldschuh and SMS were found guilty by New York City's administrative tribunal of performing laboratory tests at another New York City clinic, known as "VIP", without a requisite laboratory permit. Dr. Feldschuh personally appeared at the hearing and admitted to at least 23 violations of this type. (R. 114-20, Denial Letter, Appendix 1).

(ii) On January 22, 1991, Dr. Feldshuh again pled guilty, this time in a New York State Department of Health proceeding, to operating an unlicensed laboratory. (R. 121-26, Denial Letter, Appendix 2). Specifically, Dr. Feldschuh admitted that Idant and SMS had operated unlicensed laboratories at two different sites in Buffalo during 1990, where Idant had actually stationed unsupervised employees to perform and report laboratory tests,

despite the fact that Idant had only a New York City laboratory permit.

(iii) A DOH investigation, performed in 1994 with respect to the pending license applications, found that, even after stipulating in 1986 that it would cease unauthorized and unlicensed testing at the VIP clinic, Idant continued to perform unlicensed testing at VIP and had altered its records to conceal this activity. (Denial Letter, R. 132-77, Appendix 5-8).[4]

(iv) Idant's clinical laboratory director from 1988 to 1994, Dr. Matthew Klein, gave DOH a sworn statement that, while employed at Idant, he regularly examined Idant specimens, at his home in New Jersey, rather than on site at Idant as required by regulation. This misconduct was corroborated by statements and records from the courier service which ferried the specimens between Idant and Dr. Klein's home. (R. 178-89,

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[4] Addressing this violation, petitioner Feldschuh noted in an affidavit in the instant case (R. 762):

> Petitioners became aware of a potential violation during its self-audit in the fall of 1993 and winter of 1994 ... At that time I instructed all Idant personnel that testing was to be performed at Idant, not at VIP. When in March 1994 I became aware that Mr. Bulatao was performing testing at VIP, I contacted ... the director of VIP [and] ... she agreed that to the extent VIP desired Mr. Bulatao to perform functions on its premises ... VIP would pay Mr. Bulatao, as one of its employees for these services.

Petitioner Feldschuh thus conceded that eight years after stipulating to cease and desist from operating an unlicensed laboratory at VIP, he "discovered" that the illegal operation continued and that his response to this violation was simply to enter into an agreement with VIP enabling VIP itself to operate an unlicensed laboratory through the services of one of his employees.

Denial Letter, Appendix 9 & 10). Idant's records falsely stated that the tests were being performed on site at Idant. (*Id.*).

(v) Despite being informed by New York City's Department of Health on June 11, 1992 that its authorization to perform urine pregnancy testing was deleted from its New York City laboratory permit, Idant illegally continued to perform this test until July 1994. (R. 190-206, Denial Letter, Appendix 11).

F. The Proceedings in the State Courts

Petitioners commenced a proceeding in the Supreme Court, New York County, to review DOH's denial of its license applications. In that proceeding, petitioners alleged, *inter alia*, that they had been denied due process of law and that they were the victims of an elaborate regulatory conspiracy. (Pet. App. 12a). By an unpublished decision and order dated July 17, 1995, the New York Supreme Court denied the petition. (Pet. App. 18a-21a).

On appeal, the Appellate Division, First Department, reversed. (Pet. App. 14a-17a). Interpreting chapter 436, and without a detailed discussion of petitioners' claims of entitlement to a property interest under state or federal law, the Appellate Division concluded that the statute did not grant DOH the authority to review the applications of the former New York City licensed banks:

> Nothing in the legislation [repealing the City licensing system] suggests that any such abolition of existing operating licenses was intended .... That the State Legislature may abolish a license without providing a licensee with a hearing, as [DOH] asserts, is of little significance. We conclude that the Legislature has not done so in this instance, but has merely provided that the State Department of Health

> assume responsibility for the regulation of existing facilities[.]

(Pet. App. 16a-17a) (emphasis in original).

On appeal, the New York State Court of Appeals reversed the order of the Appellate Division, in an opinion by Chief Judge Kaye. (Pet. App. 1a-13a). Reviewing the legislative history of the 1993 amendment to Public Health Law § 574 eliminating the City licensing system, the Court of Appeals rejected the Appellate Division's holding that the Legislature had intended to "grandfather" City-licensed facilities into the State system. (Pet. App. 5a-6a). Noting the intent of the legislation to make "the requirements for certification more stringent," (Pet. App. 6a), the court found that the Appellate Division's reading of the amendment would contravene the mandate, under PHL § 575(2), that DOH refuse to license any blood bank or clinical laboratory "unless [it] finds that the clinical laboratory or blood bank is competently staffed and properly equipped, and will be operated in the manner required by this title." (Pet. App. 6a-7a). Because it would result in the granting of fully licensed status to petitioners' facilities without any review by DOH, the court held that the lower court's ruling was contrary to the general intent of the statute. (*Id.*).

The Court of Appeals carefully considered and rejected petitioners' argument that a property interest had arisen by virtue of their "years of continuous operation under the City's licensing scheme and provisional State licenses." (Pet. App. 9a-11a). Applying this Court's analytical framework set forth in *Board of Regents v. Roth*, 408 U.S. 564 (1971), the court examined both the amount of discretion that DOH enjoyed in passing upon the applications, and the nature of the discretionary criteria to be applied in such reviews, and concluded that no property right had arisen. (Pet. App. 9a-11a).

Finally, the court concluded that, in light of petitioners' past conduct, the determination to deny the applications was rational. (Pet. App. 3a-4a, 11a-13a). It rejected the claim that the denial of licenses reflected an "elaborate regulatory conspiracy" against petitioners as unsupported by the record. (*Id.*).

Petitioners subsequently filed a petition for a writ of certiorari.

ARGUMENT

IN THE ABSENCE OF ANY CONFLICT OR INCONSISTENCY BETWEEN THE DECISION OF THE COURT OF APPEALS AND THE DECISIONS OF THE FEDERAL COURTS, NO REASON EXISTS FOR THE GRANT OF CERTIORARI.

The petition for certiorari should be denied because the New York State Court of Appeals, in reaching its decision in the instant matter, correctly applied this Court's well-settled analytical principles addressing the creation of property interests under the Fourteenth Amendment. Foremost among such principles -- and virtually unmentioned in the petition -- are those set forth in this Court's ruling in *Board of Regents v. Roth*, 408 U.S. 564 (1971) (a legitimate claim of entitlement to a benefit provided by government must be rooted in existing rules or understandings "that stem from an independent source such as state law").

As we have noted above, New York State recognized two species of blood bank license prior to 1994. State licenses, authorizing operations everywhere in New York State except New York City, could issue only upon a finding by DOH that the applicant was likely to conform its operations to law. PHL

§ 575(2). The more limited City license, issued by the City Department of Health and authorizing operations only within New York City, required no such finding by DOH. During the time petitioners enjoyed their City licenses, their applications for State licenses were consistently denied on grounds of insufficient character. In 1994, New York's Legislature then abolished the entire City licensing system and imposed the DOH character and competence requirement upon petitioners and all other former holders of City licenses.

Under these facts, the Court of Appeals correctly held that petitioners had no "legitimate claim of entitlement" to State licenses under *Roth* (408 U.S. at 577-578). In light of the significant discretion granted to DOH under the statute to review applications, a DOH determination that an applicant could not be trusted to observe strictly State laws and regulations does not implicate a "property" interest or entitle the applicant to an adversarial hearing. Such a conclusion is in full accord with *Roth*, which held that the expectations of an applicant for State benefits must be legitimate and not merely a unilateral expectation. Nothing in the City licensing system, or in the legislation which abolished it, or in the State of New York's statutes or regulations, gave petitioners any guarantee or even strong expectation that DOH would automatically license them to operate, or approve their character, either before or after the repeal of the City licensing system. Petitioners' receipt of City licenses gave them no expectation of State licenses under a different statewide regulatory program. Indeed, since DOH had consistently denied all of their prior applications for State licenses, they had no basis for a belief that they would be granted licenses under the new system.

Not only have petitioners failed to demonstrate entitlement to State licenses -- they have failed even to show an entitlement to annual renewal of their City licenses prior to 1994. They made no record of the basis for such an entitlement before the courts

below, claiming only that their long operating history and the importance of the license to their operations established a property interest. (*See* Pet. App. 7a, n. 2). This is plainly insufficient under *Roth*.[5]

Petitioner's contrary contentions are meritless. Indeed, unable to address the principles of *Roth*, petitioners instead rely upon a series of cases which deal either with the revocation of licenses during their term, or which involve governmental benefits which are non-discretionary and to which an "entitlement" can therefore be said to exist. *See, e.g., Barry v. Barchi*, 443 U.S. 55 (1979) (summary suspension of an existing horse trainer's license during its term); *Bell v. Burson*, 402 U.S. 535 (1971) (suspension of an existing automobile driver license during its term); *Memphis Light, Gas & Water Div. v. Craft*, 436 U.S. 1 (1978) (non-discretionary grant to all Memphis utility customers of an absolute entitlement to receive electrical service); *Herz v. Degnan*, 648 F.2d 201 (3d Cir. 1981) (reapplication process a mere formality and approval of applications "automatic"). These cases, and the legal principles which they reflect, are simply irrelevant to the matter at bar. As the Court of Appeals correctly noted (Pet. App. 7a), "[w]hile existing licenses cannot be revoked without a hearing, there is no similar right for initial applications or renewals of licenses [citations omitted]." Moreover, as we have noted above, the statutory framework for issuance and renewal of licenses

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[5]We note in passing that the Legislature's abolition of the City's licensing authority did not violate petitioners' right to due process. *See, e.g., Atkins v Parker*, 472 U.S. 115, 129-130 (1985) (an existing, legislatively based property entitlement does not limit the legislature's power to substitute a different, less valuable entitlement at a later date). If petitioners had any conceivable entitlement to renewal of their limited City permit -- which they did not -- New York's Legislature was free to abolish that entire species of permit without violating their constitutional rights.

afforded ample discretion to the licensing authority, and provided no basis for a belief that the application process was a mere formality.

In sum, the decision of the New York State Court of Appeals is fully consistent with the decisions of this Court, the federal Courts, and well-settled principles of due process. The petition should be denied.

CONCLUSION

The Petition For A Writ Of Certiorari Should Be Denied.

Dated: New York, New York
March 18, 1998

Respectfully submitted,

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No. 97-1345

IN THE

Supreme Court of the United States

OCTOBER TERM, 1997

DAXOR CORPORATION, *et al.*,

Petitioners,

v.

STATE OF NEW YORK DEPARTMENT OF HEALTH, *et al.*,

Respondents.

On Petition for a Writ of Certiorari to the Court of Appeals of New York

PETITIONERS' REPLY BRIEF

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PETITIONERS' REPLY BRIEF

INTRODUCTION

In its opposition, the New York State Department of Health spends a great deal of effort in an attempt to justify the decision to shut down the petitioners' blood bank, tissue bank and clinical laboratories despite their continued licensure by the City of New York for as long as 25 years. The list of allegations against the petitioners is an assortment of half-truths, errors and misstatements about the conduct of the petitioners' facilities which only serve to emphasize why, under the Due Process Clause, the State

must provide a meaningful opportunity to be heard prior to terminating professional licenses based on factual determinations about the "character and competence" of the licensees.

There is no question in this case that the State has a right to revoke, withhold, or deny applications for licenses where the State properly determines that the licensee or applicant is unfit to operate blood banks, tissue banks or clinical laboratories. The issue is whether, having authorized the petitioners to operate their facilities for more than two decades, the State could properly make a negative determination about their "character and competence" and terminate their right to continue operations without providing the petitioners a fair opportunity to demonstrate that the State's perceptions were misguided and that the petitioners are, in fact, qualified for continued licensure under the standards set forth in the New York Public Health Laws. The New York Court of Appeals' decision holding that the petitioners have no rights under the Due Process Clause, notwithstanding their long-standing operations pursuant to authorizations granted under State law, is in conflict with this Court's decisions and those of the federal courts of appeals. Because this conflict involves an important issue concerning the scope of the Due Process Clause of the Fourteenth Amendment that is likely to recur, the petition for writ of certiorari should be granted.

ARGUMENT

I

THE CONFLICT IS GENUINE

The Department of Health asserts that the decision below is a straight-forward application of this Court's decision in *Board of Regents v. Roth*, 408 U.S. 564 (1972),

in which the Court held that a "property interest" under the Due Process Clause must involve a legitimate claim of entitlement to a government benefit that stems from independent sources, such as state law. Therefore, the Department of Health contends, there is no conflict between the decision below and this Court's prior rulings. The contention is wrong because *Roth* does nothing more than establish a general framework for analyzing a due process claim.

To resolve the question of whether a State can legitimately extinguish settled business expectations to continued professional licensure by shifting licensing authority from one governmental regulatory body to another, one must look beyond *Roth* to this Court's decisions in *Barry v. Barchi*, 443 U.S. 55 (1979) and *Bell v. Burson*, 402 U.S. 535 (1971). These cases, which are firmly rooted in a long line of precedent beginning with *Dent v. West Virginia*, 129 U.S. 114 (1889), establish that the operator of a business under a renewable license has a "property interest" in the continued maintenance of his business, which cannot be extinguished without minimal procedural safeguards such a hearing and an opportunity to present evidence to substantiate his qualifications to continued licensure.

The Department of Health seeks refuge from these cases by ignoring the State licensing scheme under which petitioners operated from 1971 through 1994, and focusing instead on the "considerable discretion" that the Department of Health claims to possess with respect to the approval of applications for new licenses under the 1994 amendments to the licensing statute. Having characterized the petitioners as "applicants" for licenses (despite their continued licensure and authorization to do business in New York City for more than two decades), the Department of Health argues that this Court's decisions involving

"revocation of licenses during their term" or the denial of government benefits that are "non-discretionary" have no application to the petitioners.[1] As the New York Appellate Division appropriately stated, the distinction "elevates form over substance." *See* Pet. App. B., p.16a.

Once this illusory distinction is eliminated, this case fits squarely within this Court's rulings that a State's authorization to engage in an otherwise legitimate occupation, once given, cannot be removed without due process of law. *See Barry*, 443 U.S. at 64 & n.11; *see also Schware v. Board of Bar Examiners*, 353 U.S. 232, 238-39 (1957); *Goldsmith v. United States Board of Tax Appeals*, 270 U.S. 117, 123 (1926). The contrary holding of the New York Court of Appeals conflicts squarely with these cases and with the decisions by the federal courts of appeals that apply them.

II

THE ISSUE IS IMPORTANT

The importance of the issue presented in this petition is underscored by the nature of the allegations upon which the Department of Health claims to have based its decision to terminate the petitioners' licenses, which the

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[1] In its Opposition, the Department of Health also contends that petitioners "failed even to show an entitlement to annual renewal of their City licenses prior to 1994." Cert. Opp. at 11. This contention is without merit, as there is no question that petitioners would have been entitled to a hearing upon revocation or non-renewal of their City licenses. *See* New York Public Health Law § 577[3]. Further, although the Department makes much of the fact that the City licenses required annual renewal, the "renewal" process was non-discretionary and automatic. It involved merely the submission of a card on which the licensee informed the City of its desire to renew the existing licenses.

Opposition sets forth at some length. Cert. Opp. at 5-8. The Opposition does not provide a full and fair account of the events described therein. Each event is mischaracterized and several of the charges simply are untrue. Each of these allegations could be readily explained,[2] but there is no evidence in the record to refute the charges because there is no record. There are only allegations raised by the State (which the New York Court of Appeals presumed to be true) and lawyers' arguments.

In *Dent v. West Virginia*, the Court observed that the right of every citizen of the United States to follow any lawful calling, business or profession is a "distinguishing feature of our republican institutions." *Dent*, 129 U.S. at 121. There can be no doubt that this freedom is a significant factor in the economic prosperity that the nation has enjoyed. If, however, the State can shut the doors of well-established corporations based on bald assertions about the "character and competence" of the men and women who run them, without affording any protections to

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[2] By way of example only, Dr. Feldschuh never admitted to "violations" involving the performance of tests at an "unlicensed clinic." Nor did the petitioners violate any regulations in that regard. The petitioners discovered through an internal audit that one of their employees was also performing tests at a doctor's in-office laboratory, which was fully authorized (and continues to be authorized) to perform tests that are done there. Steps were then taken to ensure that any compensation for the performance of such tests derived from the doctor who maintained the laboratory, rather than from the petitioners. Nor did the petitioners perform pregnancy tests without New York City approval. An administrative error led to the deletion of this category of tests from petitioners' licenses. City officials were informed of the error – which arose only as the result of the City's incorrect understanding that the petitioners no longer wanted to perform these tests – and the City officials said there would be no problem. During the period in question, 1992-94, the petitioners were subject to annual proficiency tests, which they passed with a 100 percent score. The flaws in the remaining allegations could similarly be readily explained if the petitioners were afforded a meaningful opportunity to explain them.

safeguard the truth or accuracy of the State's assertions, then this "distinguishing feature" of our republic no longer exists.

The right to engage in business free from arbitrary and unreasonable interference from the State – a right which even the New York Court of Appeals conceded the petitioners have (Pet. App. A., at 11a) – cannot be fulfilled if those who are engaged in business are given no meaningful opportunity to rebut the factual basis on which the State may decide to deprive them of their existence as a business within the State. *See Joint Anti-Fascist Committee v. McGrath*, 341 U.S. 123, 179 (1951) ("It is procedure that spells much of the difference between rule by law and rule by whim or caprice.") (Douglas, J., concurring). The issue presented in this petition is an important one which deserves the attention of this Court.

CONCLUSION

For the foregoing reasons, as well as those previously set forth, the petition for writ of certiorari should be granted.

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